Myovant Sciences Announces Corporate Updates and Financial Results for Third Quarter of Fiscal Year 2020

February 11, 2021

- *ORGOVYX™ (relugolix) approved by the U.S. Food and Drug Administration (FDA) in December 2020 as the first and only oral GnRH receptor antagonist for adult patients with advanced prostate cancer; ORGOVYX launched in the U.S. in early January 2021*
- *Announced collaboration with Pfizer in December 2020 to jointly develop and commercialize relugolix in oncology and relugolix combination tablet in women's health in the U.S. and Canada*
- *Reported positive one-year efficacy and safety data from Phase 3 SPIRIT program for relugolix combination therapy in women with endometriosis-associated pain, including bone mineral density data*
- *FDA review of New Drug Application for relugolix combination tablet for uterine fibroids remains on track for a decision by June 1, 2021 target action date; European Commission decision on uterine fibroids Marketing Authorization Application expected in mid-calendar year 2021*
- *Announced Phase 3 SERENE study to assess the contraceptive efficacy of relugolix combination tablet; study designed to support potential benefit of prevention of pregnancy for women taking relugolix combination tablet for the treatment of uterine fibroids and endometriosis, if approved for those indications*
- *Cash, cash equivalents, and marketable securities of $745.8 million as of December 31, 2020*

BASEL, Switzerland, Feb. 11, 2021 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced corporate updates and financial results for the third quarter of fiscal year 2020.

"The FDA approval of ORGOVYX and the landmark collaboration with Pfizer represent pivotal catalysts that have advanced Myovant's purpose of redefining care and its transformation into a commercial-stage company with compelling near-term opportunities in oncology and women's health," said David Marek, Chief Executive Officer of Myovant Sciences, Inc. "We are encouraged by the early launch progress for ORGOVYX and expect this momentum to continue to build with the Pfizer uro-oncology sales team recently joining the Myovant sales team in the field. ORGOVYX has the potential to become the new androgen deprivation therapy standard of care in advanced prostate cancer. Combined with relugolix combination tablet, if approved in uterine fibroids and endometriosis, these products are expected to drive significant revenue growth for Myovant in the years to come."

Third Quarter Fiscal Year 2020 and Recent Corporate Updates

Pfizer Collaboration

- In December 2020, Myovant entered into a collaboration agreement with Pfizer under which Myovant and Pfizer will jointly develop and commercialize relugolix in oncology and women's health and equally share profits and certain expenses, in the U.S. and Canada (the Co-Promotion Territory).
- In December 2020, Myovant received a $650.0 million upfront payment and is eligible to receive additional regulatory and sales milestones, for total net payments of up to $4.2 billion.
- Myovant granted Pfizer an exclusive option to acquire development and commercialization rights to relugolix in oncology outside of the Co-Promotion Territory (excluding certain Asian markets). If Pfizer exercises this option, Myovant will receive an additional $50.0 million payment and will be eligible to receive double-digit royalties on net sales. Pfizer's decision is expected in the first half of calendar year 2021.

ORGOVYX

- On December 18, 2020, the U.S. Food and Drug Administration (FDA) approved ORGOVYX for the treatment of adult patients with advanced prostate cancer. ORGOVYX, which was granted Priority Review by the FDA, is the first and only oral GnRH receptor antagonist for men with advanced prostate cancer.
- ORGOVYX was launched in the U.S. and authorized specialty distribution channels were fully stocked in early January 2021.
- The ORGOVYX patient support program launched in early January, including access to free trial for new commercial and government insured patients and co-pay support for eligible commercial patients.

- Myovant completed the hiring of its 100-person oncology sales force during December 2020. All sales professionals completed training and began actively promoting ORGOVYX to target prescribers in early January 2021.
- Pfizer's uro-oncology sales force was trained in January 2021 and began actively promoting ORGOVYX to target prescribers in early February 2021.
- Myovant is engaging in coverage negotiations with key commercial and Medicare Part D payors, with some coverage anticipated by the middle of calendar year 2021 and broad coverage anticipated by the end of calendar year 2021.

Relugolix Combination Tablet

- ***Uterine Fibroids***
  - In October 2020, Myovant presented the following data for relugolix combination therapy in women with uterine fibroids at the American Society for Reproductive Medicine (ASRM) 2020 Virtual Congress:

    - One-year efficacy and safety data from the LIBERTY long-term extension study (Scientific Congress Prize Paper Session 1).

    - A validated exposure-response model simulating long-term effects of relugolix combination therapy on bone mineral density at the lumbar spine.

    - A poster describing the improvement of pain associated with uterine fibroids in the LIBERTY Phase 3 program (1st Place in Poster Competition).

- ***Endometriosis***
  - In October 2020, data from the replicate Phase 3 SPIRIT 1 and SPIRIT 2 studies were presented at the ASRM 2020 Virtual Congress in an oral presentation named the Prize Paper by the Endometriosis Special Interest Group.
  - In January 2021, Myovant and Pfizer announced positive one-year data from the SPIRIT extension study of once-daily relugolix combination therapy in women with endometriosis. 84.8% and 73.3% of women reported clinically meaningful reductions in dysmenorrhea (menstrual pain) and non-menstrual pelvic pain over one year (52 weeks) with stable bone mineral density after initial minimal loss. The data are consistent with the efficacy and safety profile observed through 24 weeks in the Phase 3 SPIRIT 1 and SPIRIT 2 studies.
  - The results of the SPIRIT clinical program will support a New Drug Application (NDA) for relugolix combination tablet for the treatment of women with endometriosis, anticipated to be submitted to the FDA in the first half of calendar year 2021.

CEO Appointment

- In January 2021, Myovant announced the appointment of David Marek as Chief Executive Officer of Myovant Sciences, Inc. Concurrent with this appointment, Mr. Marek was also appointed as Principal Executive Officer of Myovant Sciences Ltd. and as a member of its Board of Directors.

COVID-19 Pandemic Environment

- Myovant's priorities during the COVID-19 pandemic are protecting the health and safety of its employees and patients while continuing its mission to redefine care for women and for men. To date, the impact of the COVID-19 pandemic on Myovant's ability to advance its clinical studies, regulatory activities, commercial launch activities for ORGOVYX, and preparations for the potential commercialization of relugolix combination tablet has been limited, and all of Myovant's publicly announced milestones remain on track. At this time, Myovant does not believe that the COVID-19 pandemic has disproportionately impacted it relative to other companies in Myovant's industry and the medical community appears to be highly engaged with Myovant's field team. To date, Myovant has not experienced supply constraints, and believes it has procured sufficient quantities of relugolix drug substance to meet its U.S. ORGOVYX launch plans and U.S. launch plans for relugolix combination tablet, if approved. However, if the COVID-19 pandemic persists, and depending on the further evolution of the pandemic and its effects on Myovant's activities, Myovant may experience more significant impacts on its business operations.

Expected Upcoming Milestones

- Data from the LIBERTY randomized withdrawal study, including efficacy and safety data of relugolix combination therapy in women with uterine fibroids for up to two years, is expected in the first quarter of calendar year 2021.
- Marketing Authorization Application (MAA) submission to the European Medicines Agency (EMA) for relugolix monotherapy

for advanced prostate cancer expected in the first quarter of calendar year 2021.

- Myovant and Pfizer plan to initiate in the first half of calendar year 2021 a Phase 3 open-label clinical study in the U.S. to assess the contraceptive efficacy of relugolix combination tablet. The SERENE study will enroll sexually active, healthy premenopausal women ages 18-35 years with presumed normal fertility. Women will receive once-daily relugolix combination tablet for 13 28-day cycles. The primary efficacy endpoint will be the Pearl Index, defined as the number of on-treatment pregnancies per 100 women-years of treatment. Positive data from the SERENE study would further differentiate relugolix combination tablet by potentially adding the benefit of prevention of pregnancy for women taking relugolix combination tablet for the treatment of uterine fibroids and endometriosis, if approved for these indications.
- FDA decision for relugolix combination tablet for the treatment of uterine fibroids expected by June 1, 2021 target action date.
- NDA submission to the FDA for relugolix combination tablet for the treatment of women with endometriosis-associated pain expected in the first half of calendar year 2021.
- European Commission decision on the uterine fibroids MAA expected in mid-calendar year 2021. If approved, this launch will be executed by Gedeon Richter, Myovant's commercialization partner for relugolix combination tablet for the uterine fibroids and endometriosis indications in Europe and certain other international markets.
- MAA submission to EMA for relugolix combination tablet for the treatment of women with endometriosis-associated pain expected in calendar year 2021. Gedeon Richter will be the MAA sponsor.

Third Quarter Fiscal Year 2020 Financial Summary

Collaboration revenue in the three months ended December 31, 2020, was $1.4 million and represents partial amortization of the upfront payment received from Pfizer.

Research and development (R&D) expenses in the three months ended December 31, 2020, were $30.5 million compared to $48.9 million for the comparable prior year period. The decrease in R&D expenses reflects a reduction in clinical study costs as a result of the completion and continued wind down of Myovant's Phase 3 LIBERTY, HERO, and SPIRIT studies, cost reimbursements from Pfizer for certain R&D expenses, and a reduction in share-based compensation expenses. This decrease was partially offset by an increase in personnel expenses, mainly driven by the continued expansion of Myovant's medical affairs organization, in preparation for Myovant's U.S. commercial launch of ORGOVYX for adult patients with advanced prostate cancer and the potential U.S. commercial launches of relugolix combination tablet for the women's health indications, if approved.

Selling, general, and administrative (SG&A) expenses in the three months ended December 31, 2020, were $49.2 million compared to $29.1 million for the comparable prior year period. The increase was primarily due to higher expenses related to commercial readiness activities to support the ORGOVYX U.S. commercial launch and the potential U.S. commercial launches of relugolix combination tablet as well as higher personnel-related costs primarily due to the hiring of Myovant's commercial operations, marketing, market access teams, and the oncology sales force. The increase in SG&A expenses was also driven by general overhead expenses to support Myovant's organizational growth. These items were partially offset by lower share-based compensation expenses in the three months ended December 31, 2020, as the prior year period included incremental expense related to the accelerated vesting of certain equity awards as a result of the change in control of Myovant.

Interest expense was $2.6 million in the three months ended December 31, 2020, compared to $3.7 million in the comparable prior year period. The decrease in interest expense, despite higher outstanding loan balances, was driven by the significantly lower interest rates associated with the Sumitomo Dainippon Pharma Loan Agreement as compared to Myovant's previously outstanding debt obligations, which were repaid in December 2019.

Loss on extinguishment of debt in the three months ended December 31, 2019 was $4.9 million which resulted from the early retirement of Myovant's outstanding obligations to NovaQuest and Hercules. There were no such losses in the three months ended December 31, 2020.

Interest income in the three months ended December 31, 2020, was less than $0.1 million compared to $0.6 million for the comparable prior year period. The decrease was primarily due to decreases in interest rates and lower balances in cash equivalents and marketable securities during the current year period.

Other income, net in the three months ended December 31, 2020, was $5.9 million compared to $0.6 million for the comparable prior year period. This was primarily the result of a larger foreign currency exchange gain on Myovant's outstanding balance under the Sumitomo Dainippon Pharma Loan Agreement during the three months ended December 31, 2020.

Net loss for the three months ended December 31, 2020, was $73.8 million compared to $85.6 million for the comparable prior year period. On a per common share basis, net loss was $0.82 and $0.96 for the three months ended December 31, 2020, and 2019, respectively.

Capital resources: Cash, cash equivalents, marketable securities, and committed amounts available under the Sumitomo Dainippon Pharma Loan Agreement totaled $832.1 million as of December 31, 2020, and consisted of $745.8 million of cash, cash equivalents, and marketable securities and $86.3 million of available borrowing capacity under the Sumitomo Dainippon Pharma Loan Agreement.

Conference Call

As previously announced, Myovant will hold a webcast and conference call at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time) today, February 11, 2021, to discuss corporate updates and financial results for its third fiscal quarter ended December 31, 2020. Investors and the general public may access a live webcast of the call by visiting the investor relations page of Myovant's website at investors.myovant.com. Institutional investors and analysts may also participate in the conference call by dialing 1-800-532-3746 in the U.S. or +1-470-495-9166 from outside the U.S.

The webcast will be archived on Myovant's Investor Relations website following the call.

About Relugolix
Relugolix is a once-daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces testicular testosterone, a hormone known to stimulate the growth of prostate cancer, and ovarian estradiol, a hormone known to stimulate the growth of uterine fibroids and endometriosis. Relugolix (120 mg) is FDA-approved as ORGOVYX™ for adult patients with advanced prostate cancer. Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is under regulatory review in Europe and the U.S. for women with uterine fibroids and is under development for women with endometriosis.

About Myovant Sciences
Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. We have one FDA-approved medicine, ORGOVYX™ (relugolix), for adult patients with advanced prostate cancer. Our lead product candidate, relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg), is under regulatory review in Europe and the U.S. for women with uterine fibroids and is under development for women with endometriosis. Myovant is also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for female infertility as part of assisted reproduction. Sumitovant Biopharma, Ltd., a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is Myovant's majority shareholder. For more information, please visit our website at www.myovant.com. Follow @Myovant on Twitter and LinkedIn.

About Sumitomo Dainippon Pharma Co., Ltd.
Sumitomo Dainippon Pharma is among the top-ten listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including the U.S., Japan, China, and the European Union. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has more than 6,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at https://www.ds-pharma.com.

About Sumitovant Biopharma Ltd.
Sumitovant is a global biopharmaceutical company with offices in New York City and London. Sumitovant is the majority shareholder of Myovant and Urovant, and wholly owns Enzyvant, Spirovant and Altavant. Sumitovant's promising pipeline is comprised of early-through late-stage investigational medicines across a range of disease areas targeting high unmet needs. Sumitovant is a wholly owned subsidiary of Sumitomo Dainippon Pharma. For further information about Sumitovant, please visit https://www.sumitovant.com.

Forward Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In this press release, forward-looking statements include, but are not limited to, all statements reflecting Myovant Sciences' expectations, including: statements regarding Myovant's aspiration to redefine care for women and for men; those statements in Mr. Marek's quote; the expectation of Pfizer's decision with respect to its exclusive option to acquire development and commercialization rights to relugolix in oncology outside of the Co-Promotion Territory; Myovant's expectations regarding potential regulatory and sales milestones from Pfizer; Myovant's expected timelines of coverage decisions by commercial and Medicare Part D payors; the expected timing and characterization of the results from Myovant's ongoing clinical trials, including the planned SERENE study; the timing of Myovant's regulatory submissions and anticipated regulatory review results; the statement that all of Myovant's publicly announced milestones remaining on track; the statements regarding the effects of COVID-19 on Myovant's operations; and those statements under the caption "Expected Upcoming Milestones." Myovant Sciences' forward-looking statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements, including unforeseen circumstances or other disruptions to normal business operations arising from or related to the COVID-19 pandemic. Myovant Sciences cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements. Factors that could materially affect Myovant Sciences' operations and future prospects or which could cause actual results to differ materially from expectations include, but are not limited to the risks and uncertainties listed in Myovant Sciences' filings with the United States Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in Myovant Sciences' Quarterly Report on Form 10-Q to be filed on February 11, 2021, as such risk factors may be amended, supplemented or superseded from time to time. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for Myovant Sciences' management to predict all risk factors, nor can Myovant Sciences assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. You should not place undue reliance on the forward-looking statements in this press release, which speak only as of the date hereof, and, except as required by law, Myovant Sciences undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements.

MYOVANT SCIENCES LTD.
Condensed Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share data)

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2020	2019	2020	2019
Revenues:				
Collaboration revenue	$ 1,379	$ —	$ 1,379	$ —
License and milestone revenue	—	—	33,333	—
Total revenues	1,379	—	34,712	—
Operating expenses:				
Research and development [1]	30,453	48,927	115,160	150,847
Selling, general and administrative [1]	49,243	29,142	103,387	59,897
Total operating expenses	79,696	78,069	218,547	210,744
Loss from operations	(78,317)	(78,069)	(183,835)	(210,744)

Interest expense	2,609	3,657	6,908	11,238
Loss on extinguishment of debt	—	4,851	—	4,851
Interest income	(32)	(597)	(178)	(2,305)
Other income, net	(5,891)	(567)	(16,178)	(1,151)
Loss before income taxes	(75,003)	(85,413)	(174,387)	(223,377)
Income tax (benefit) expense	(1,154)	191	(616)	699
Net loss	$ (73,849)	$ (85,604)	$ (173,771)	$ (224,076)
Net loss per common share — basic and diluted	$ (0.82)	$ (0.96)	$ (1.94)	$ (2.64)
Weighted average common shares outstanding — basic and diluted	90,096,557	88,893,579	89,715,160	84,750,114
[(1)] Includes the following share-based compensation expenses:				
Research and development	$ 3,311	$ 5,399	$ 11,060	$ 11,565
Selling, general and administrative	$ 3,699	$ 14,396	$ 10,686	$ 22,613

MYOVANT SCIENCES LTD.
Condensed Consolidated Balance Sheets
(Unaudited, in thousands)

	December 31, 2020	March 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 713,523	$ 76,644
Marketable securities	32,324	2,997
Prepaid expenses and other current assets	8,180	8,269
Total current assets	754,027	87,910
Property and equipment, net	2,847	2,497
Operating lease right-of-use asset	10,045	11,146
Other assets	7,295	4,373
Total assets	$ 774,214	$ 105,926
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	$ 12,357	$ 15,334
Interest payable (related party)	—	15
Accrued expenses	44,377	29,060
Deferred revenue	100,564	40,000
Cost share advance from collaboration partner	92,415	—
Operating lease liability	1,731	1,516
Amounts due to related parties	628	—
Total current liabilities	252,072	85,925
Deferred rent, non-current	418,344	—
Cost share advance from collaboration partner, non-current	46,424	—
Long-term operating lease liability	9,669	10,996
Long-term debt, less current maturities (related party)	313,700	113,700
Other	4,662	3,582
Total liabilities	1,044,871	214,203
Total shareholders' deficit	(270,657)	(108,277)
Total liabilities and shareholders' deficit	$ 774,214	$ 105,926

Investor Contact:
Ryan Crowe
Vice President, Investor Relations
Myovant Sciences, Inc.
+1 (650) 781-9106
investors@myovant.com

Media Contact:
Albert Liao

Director, Corporate Communications
Myovant Sciences, Inc.
+1 (650) 410-3055
media@myovant.com

Source: Myovant Sciences, Inc.